

Message Text

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ACTION EA-12

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E.O. 11652: NA
TAGS: BEXP, JA
SUBJECT: TRADE FACILITATION COMMITTEE: CASE NO. 4--
ABBOTT LABORATORIES

REF: (A) STATE 160438, (B) TOKYO 11301

1. SUMMARY: DURING JULY 6 MEETING, MHW PHARMACEUTICAL AFFAIRS BUREAU DIRGEN NAKANO STATED THAT IN VIEW OF THE ABBOTT CASE'S POLITICAL CONSIDERATIONS, MHW WOULD MOVE TO ACCELERATE ITS APPROVAL PROCEDURES FOR AUSRIA AND COMPLETE THE PROCESS BY THE END OF JFY 1978 (MARCH 1979). NAKANO AGREED THAT JAPAN RED CROSS (JRC) USE OF AUSRIA AS A PUBLIC CLINICAL TEST AND ITS APPROVAL BY MHW ARE SEPARATE ISSUES. HOWEVER, HE MAINTAINED NOT ONLY THAT THE JRC MUST DECIDE FOR ITSELF WHETHER TO SELECT THE ABBOTT PRODUCT, BUT THAT THE JRC HAS YET TO FORMALLY REQUEST MHW FUNDS NECESSARY FOR MEETING THE INCREASED COST OF AUSRIA'S USE. WHILE WE WILL MEET AGAIN WITH MHW TO CLARIFY APPARENT MISUNDERSTANDINGS CONCERNING THE JRC AND AUSRIA, WE ARE CONCERNED BY THE APPEARANCE OF EMBASSY PRESSURE ON THE GOJ TO PROVIDE PUBLIC FUNDS FOR SUPPORTING THE SALE OF A COMMERCIAL U.S. PRODUCT, THE ACTUAL
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DEMAND FOR WHICH BY THE JRC HAS YET TO BE CONCLUSIVELY PROVEN. END SUMMARY.

2. IN A FOLLOW-UP TO THE AMBASSADOR'S CALL ON MHW MINISTER OZAWA, WE DISCUSSED ABBOTT CASE WITH MHW PHARMACEUTICAL AFFAIRS BUREAU (PAB) DIRECTOR GENERAL NAKANO ON JULY 6. NAKANO FIRST EXPRESSED REGRET THAT

THE ABBOTT CASE HAS BEEN INTERPRETED AS A "TRADE BARRIER" PROBLEM AND NOTED THAT THE GOJ HAS NO INTENTION OF BLOCKING U.S. PHARMACEUTICAL EXPORTS TO JAPAN. NAKANO EMPHASIZED THAT MHW APPROVAL FOR AUSRIA IS A MATTER OF TECHNICAL PROCEDURE INDEPENDENT OF TRADE CONSIDERATIONS. STILL, HE SAID, GIVEN THIS CASE'S POLITICAL DIMENSIONS, MHW IS READY TO ACCELERATE ITS APPROVAL PROCEDURES, WITH A GOAL OF COMPLETING THE PROCESS BY THE END OF JFY 1978; THAT IS, END OF MARCH, 1979 (WHICH WE UNDERSTAND TO BE SEVERAL MONTHS EARLIER THAN THE TIME OF APPROVAL ORIGINALLY ANTICIPATED). WHEN ASKED ABOUT THE POSSIBILITY OF FACILITATING APPROVAL PROCEDURES THROUGH USE OF U.S. DATA AND EQUIPMENT NAKANO SIMPLY SAID THAT HE WOULD LIKE DAINABOT PERSONNEL TO MAINTAIN CLOSER CONTACT WITH MHW ON SUCH PROBLEMS.

3. NAKANO READILY AGREED WITH ABBOTT'S ASSERTION THAT JRC USE OF AUSRIA AS A PUBLIC CLINICAL TEST IS A SEPARATE ISSUE FROM ITS APPROVAL BY MHW. HOWEVER, HE STRESSED THAT THE JRC MUST DECIDE FOR ITSELF WHETHER TO ADOPT AUSRIA. WHILE MHW CANNOT INFLUENCE THE DECISION ITSELF, IT WOULD HAVE TO APPROVE FUNDS NEEDED BY THE JRC TO MEET THE INCREASED EXPENSE OF USING AUSRIA RATHER THAN RPHA. NAKANO SAID THAT MHW WOULD CONSIDER A JRC REQUEST FOR SUCH FUNDS WHEN THE JRC ACTUALLY DECIDES TO ADOPT AUSRIA AS A PUBLIC CLINICAL TEST--IN RESPONSE TO A DIRECT LIMITED OFFICIAL USE

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QUESTION, HE STATED FLATLY THAT NO SUCH FORMAL REQUEST HAS BEEN RECEIVED.

4. COMMENT: ON THE DAY BEFORE THIS MEETING, A WORKING-LEVEL OFFICIAL OF PAB'S BIOLOGICS DIVISION VISITED US TO SOUND OUT OUR OBJECTIVES IN CALLING ON NAKANO. HIS COMMENTS INDICATED NOT ONLY A HIGH STATE OF APPREHENSION AMONG MHW OFFICIALS, BUT A CONTINUED LACK OF UNDERSTANDING CONCERNING THE ABBOTT CASE'S WIDER IMPLICATIONS. THIS ATTITUDE WAS EVIDENT DURING THE MEETING ITSELF--WHILE NOT UNFRIENDLY, NAKANO WAS VERY CAUTIOUS AND HIS REMARKS DID NOT IN FACT VARY SIGNIFICANTLY FROM EARLIER MHW STATEMENTS ON ABBOTT. THE ISSUE OF JRC ADOPTION OF AUSRIA IS PARTICULARLY CONFUSING. THERE IS A CLEAR CONTRADICTION BETWEEN NAKANO'S ASSERTION THAT MHW HAS NOT BEEN APPROACHED BY JRC ON AUSRIA AND ABBOTT EVIDENCE OF MHW-JRC CONTACT ON THIS SUBJECT. WE WILL USE OUR EXPANDED CONTACTS WITHIN THE PAB TO TRY AND RESOLVE THIS MISUNDERSTANDING.

5. EMPHASIS ON JRC USE OF AUSRIA IN ADDITION TO ITS APPROVAL BY MHW AS A CENTRAL ISSUE IN THE ABBOTT CASE

RAISES WHAT COULD BE A SERIOUS PROBLEM. GIVEN THE JRC'S
NEED FOR MHW FUNDS TO MEET AUSRIA'S ADMITTEDLY HIGHER
COST AND THE ABSENCE OF CONCLUSIVE EVIDENCE THAT THE JRC
HAS STATED A "COMPETITIVE" PREFERENCE FOR AUSRIA OVER
ITS OWN RPHA, WE ARE IN NO POSITION TO PRESS MHW FOR
THE RELEASE OF PUBLIC FUNDS TO SUBSIDIZE ADOPTION OF A
PRIVATE, COMMERCIAL U.S. PRODUCT. IT IS ONE THING TO
ARGUE ON PRINCIPLE FOR REASONABLE, NON-DISCRIMINATORY
APPROVAL PROCEDURES, BUT QUITE ANOTHER TO APPEAR AS A
SALES AGENT FOR AUSRIA TO THE GOJ AND THE JAPANESE
MEDICAL PROFESSION.
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